K131124

*Annex 2*- 510(k) summary

**1 Submitter**

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AUG 2 8 2013

**2 Device**

| | |
|---|---|
| Trade name: | CoLign™ Hemostasis Valve |
| Common Name: | Hemostatic Valve |
| Classification Name: | Cardiopulmonary Bypass Adaptor, Stopcock, Manifold or Fitting |
| Classification: | Class II |
| Regulation Number: | 870.4290 |
| Product code: | DTL |

**3 Predicate Device**

The predicate devices is used to determine the substantial equivalence between the CoLign Hemostasis Valve and the EasyPass™ Y-connector Hemostatic Valve marketed by Millimed A/S(# K042060)

**4 Device Description**

The CoLign Hemostasis Valve is a device that can be operated with only one hand through its special "push-pull" mechanism. In the pushed-down position, the valve is open for safe insertion and removal of devices. In the pulled-up position, the valve is closed and seals smoothly round the inserted devices. Once the valve is closed, devices can still be manipulated freely. CoLign eliminates the need for adjustment of the hemostasis valve by rotating during the procedure. The CoLign Hemostasis Valve is compatible with most interventional devices based on rapid exchanged and over-the-wire technology. There are three models of the CoLign Hemostasis Valve: the Standard CoLign , the CoLign 20,and the CoLign 50. The configuration of the sideport is the only difference among the three models. The sideport of the Standard CoLign ends in a male luer, while the sidearm of the CoLign 20/50 ends with a 20/50 cm extension tubing and 3-way stopcock.

**5 Intended Use**

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The CoLign™ Hemostasis Valve is intended to maintain hemostasis during the introduction/withdrawal and use of diagnostic and interventional devices up to an external diameter of 7 French or smaller.

The insertion tool facilitates introduction of the guide wire through the hemostasis valve.

The torque when inserted into the proximal end of the guide wire provides a handle for easier manipulation of the guide wire.

**6 Comparisons of Technological Characteristics**

Comparing CoLign Hemostasis Valve with the predicate devices, it has shown that the technological characteristics of the CoLign Hemostasis Valve such as materials used, performance, and sterilization are identical or substantially equivalent to the currently marketed predicate device method.

| **General Information** | **CoLign™** | ***EasyPass™*** |
|---|---|---|
| **Manufacturer** | Jilin Coronado Medical Ltd | Millimed A/S |
| **Intended Use** | CoLign Hemostatic Valve is intended to maintain hemostasis during the introduction, use and withdrawal of diagnostic and interventional devices that have an outer diameter of 7 French or smaller. | Same |
| **Operational Principle** | Pull-push valve with one-hand operation | Pull-push valve opener enables single handed control |
| **Sterilization Method** | ETO | ETO |
| **Sub-component function design** | **CoLign™** | ***EasyPass™*** |
| **Y-hub** | Main body of the product | Same |
| **Bridge valve** | Holding the silicone valve in place | Similar Design |
| **Hemositatic valve sandwich** | Maintain sealing with or without products inserted througth the valve | Similar Design |
| **Valve opener** | Mechanic opening of the silicone valve, by pushing a hollow tube through the valve | Same |
| **Extension-tube** | Functions as an extension of the product to be connected with additional accessories | Same |

| | | |
|---|---|---|
| **3-Way Stopcock** | Enabling joining of accessories to the distal end of the PU-tube | Same |
| **Introducer Needle (Accessory)** | Ensure a safe passage of product through the silicone valve | Same |
| **Torquer Device (Accessory)** | Ensure better handling of guide wires | Same |
| **Specification comparison** | **CoLign™** | **Eas Pass™** |
| **Optimal inner lumen** | 7 French (2.33mm/0.092") | 7 French (2.33mm/0.092") |
| **Inner diameter of narrowest portion** | 7.2F/2.4mm/0.094" | 7.2F/2.4mm/0.094" |
| **Diameter of device to inserted** | Maximum 7F/2.33MM/0.092" Minimum 0.53F/0.17mm/0.007" | Maximum 7F/2.33MM/0.092" Minimum 0.53F/0.17mm/0.007" |
| **Pressure resistance with catheter and guidewire** | 8bar | 8bar |
| **Pressure resistance without device** | 20bar | 21bar |
| **Component material** | **CoLign™** | ***EasyPass™*** |
| **Valve Body** | Poly carbonate | Poly carbonate |
| **O-ring** | Silicone | Silicone |

**7 Performance Data**

The results of the performance testing have demonstrated of the CoLign™ Hemostasis Valve.

- Visual Inspection for Pouch Integrity
- Pouch Peel Test
- Leak Test without products inserted
- Leak test with guide wire and hypo tube inserted
- Pressure Resistance Test
- Tensile test on assembly of PU tube/PC fitting
- Product Stability (Shelf Life)
- Product Sterilization
- Biocompatibility Testing (all the test met the requirements specified in ISO 10993)
  - Hemolysis
  - Pyrogenicity

**8 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data**

The performance test data of the non-clinical tests supports the substantial equivalence between CoLign Hemostasis Valve and the predicate device mentioned immediately above.

## 9 Conclusion

It can be concluded that the CoLign Hemostasis Valve has demonstrated the substantial equivalence to the predicate devices with respect to intended use, technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES · Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 28, 2013

Jilin Coronado Medical, Ltd.
Ms. Nicole Ma
Regulatory Specialist
9 South-west Ring Road
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Jilin City, China 132016

Re: K131124
Trade/Device Name: CoLign Hemostasis Valve
Regulation Number: 21 CFR 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
Regulatory Class: Class II
Product Code: DTL
Dated: May 27, 2013
Received: June 03, 2013

Dear Ms. Ma:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. However, we remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for
Bram D. Zuckerman, MD
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

***Annex 1***- Indication for Use Statement

510(k) Number (if known): K131124 Device

Name: CoLign™ Hemostasis Valve

The CoLign™ Hemostasis Valve is intended to maintain hemostasis during the introduction/withdrawal and use of diagnostic and interventional devices up to an external diameter of 7 French or smaller.

The insertion tool facilitates introduction of the guide wire go through the hemostasis valve.

The torquer when inserted into the proximal end of the guide wire provides a handle for easier manipulation of the guide wire.

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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**Concurrence of CDRH, Office of Device Evaluation (ODE)**